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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/430,050

10/29/1999

MICHAEL S.H. CHU

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04/11/2003

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EXAMINER

LAM, ANN Y

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 04/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Applicati n N .

09/430,050

Applicant(s)

CHU ET AL.

Examiner

Ann Y. Lam

Art Unit

3763

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-9, 11-15 and 21.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

 4/8/03

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments are not persuasive. Applicant argues that element (300) disclosed by Heck is not a compressible valve sleeve, and the device disclosed by Heck is not designed to compress element (300). Applicant points to a passage in column 2, lines 14-32 and emphasizes that Heck states that "squeezing the exposed end of the sheath can deform or even break the sheath, making lead insertion difficult and increasing the likelihood of damage to the lead as it passes through the sheath", (Heck, column 2, lines 27-30), to support Applicant's position that Heck teaches that the sheath and/or lead are not supposed to be compressed, see page 3 of Applicant's arguments. In response, Examiner notes that the above passage which Applicant emphasizes refers to a physician placing his thumb over the exposed end of the sheath or squeezing or pinching the exposed end of the sheath to limit the flow of blood out of the sheath, see column 2, lines 14-18. In other words, the cited passage does not teach that the disclosed valve must not squeeze or pinch the sheath or lead. To the contrary, the whole purpose of the valve is to squeeze or pinch the lead or other medical device, such as a catheter, see column 5, lines 33-35, and column 9, lines 17-24, such that "the two body sections (26, 28) are forced together to hold securely the components of the partitioned hemostasis valve housing (12) together in a closed position and reduce the likelihood of leakage of blood from the partitioned hemostasis valve system (10)", column 8, lines 24-30, and such that "[b]ecause the hemostasis valve sections (38, 40) are forced together, the partitioned hemostasis valve (14) acts like a conventional hemostatis valve, minimizing the amount of blood loss during the procedur ", column 9, lines 31-34. In other words, the valve pinches the lead or other medical device such as a catheter, which Examiner asserts is compressible and is compressed in operation of the hemostasis valve, in order to prevent leakage of blood. Furthermore, the fact that the "sloped portion (60) provides space for the lips (56) to separate without excessive force being applied, as the medical device passes through the lips (56)", see column 6, lines 43-53, does not mean that the lips (56) do not pinch the lead or catheter positioned in the valve. Examiner reasserts that such pinching is required in the Heck device in order for the device to prevent leakage of blood as disclosed in the Heck specification



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